

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparing the effect of acupuncture and traditional pharmacologic therapy on Delayed Gastric Emptying on traumatic patient in ICU of BESAT Hospital, Hamadan

#### Protocol summary

##### Summary

Objective: Comparing the effect of acupuncture and traditional pharmacologic therapy on Delayed Gastric Emptying on traumatic patient in ICU. Design: Double blind clinical trial. Population: 60 people from traumatic patients (multiple trauma and head trauma) who are admitted in ICU . Inclusion criteria: All trauma patients ranges from 18 to 75 years of age who are admitted in ICU and their conditions suitable for Enteral feeding and have Tube feeding intolerance. Exclusion criteria : Not Satisfied to perform acupuncture, Patients who have contraindications to enteral feeding, age younger than 18 years or older than 75 years, Patients are prohibitive for NG Tube insertion recent major abdominal surgery, , suspected bowel obstruction or perforation, pancreatitis. In the group receiving the drug: Erythromycin 200mg every 6 hours (syrup) will be used as standard drug. If appropriate response is not seen in patients Metoclopramide as supplemental drug dose 10-20 mg every 8 hours will be used. Acupuncture patient groups: stimulation at frequencies between 7 to 13 MA current 7HZ (depending on the patient's wrist width) is performed. The two stimulation for 20 min and at intervals of every 12 hours (twice a day) for 6 days at the P6 acupuncture point and at a depth of 0.5 cm from the skin surface is performed. Improved as the volume of gastric residual volume less than 200 cc in 24 hours - which is obtained through NGTube - is determined in two consecutive days.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112014578N4**

Registration date: **2012-02-27, 1390/12/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-02-27, 1390/12/08

##### Registrant information

###### Name

Farshid Rahimibashar

###### Name of organization / entity

Hamedan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 811264002151

###### Email address

f.rahimi@umsh.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Hamedan University of Medical Sciences-vice chancellor for research

##### Expected recruitment start date

2012-02-20, 1390/12/01

##### Expected recruitment end date

2012-11-20, 1391/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of acupuncture and traditional pharmacologic therapy on Delayed Gastric Emptying on traumatic patient in ICU of BESAT Hospital, Hamadan

##### Public title

The effect of acupuncture and traditional pharmacologic therapy on Delayed Gastric Emptying

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: All trauma patients ranges from 18 to 75 years of age who are admitted in ICU and his conditions suitable for Enteral feeding and has Tube feeding intolerance. postoperative days. Exclusion criteria : Not Satisfied to perform acupuncture Patients who have contraindications to enteral feeding age younger than 18 years or older than 75 years, Patients are prohibitive for NG Tube insertion recent major abdominal surgery, history of partial or total gastrectomy, suspected bowel obstruction or perforation, pancreatitis, administration of prokinetic drugs (Metoclopramide, cisapride, or erythromycin) within the previous 24 hours.

### **Age**

From **18 years** old to **75 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Hamedan University Of Medical Sciences

##### **Street address**

Mahdiye Street, Hamedan University Of Medical Sciences

##### **City**

Hamedan

##### **Postal code**

#### **Approval date**

2011-12-10, 1390/09/19

#### **Ethics committee reference number**

16/35/9/3244/د/پ

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

gastroparesis

#### **ICD-10 code**

K31

#### **ICD-10 code description**

Other diseases of stomach and duodenum

## **Primary outcomes**

### **1**

#### **Description**

Volume remaining in the stomach.

#### **Timepoint**

Total volume remaining in the stomach during a day

#### **Method of measurement**

Through the NG tube attached to the patient

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Acupuncture patient groups: stimulation at frequencies between 7 to 13 mA current 7HZ (depending on the patient's wrist width) is performed. The two stimulation for 20 min and at intervals of every 12 hours (twice a day) for 6 days at the P6 acupuncture point and at a depth of 0.5 cm from the skin surface is performed.

#### **Category**

Treatment - Devices

### **2**

#### **Description**

In the group receiving the drug: Erythromycine 200mg every 6 hours (syrup) will be used as standard drug. If appropriate response is not seen in patients Metoclopramide as supplemental drug dose 10-20 mg every 8 hours will be used.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Besat Hospital

##### **Full name of responsible person**

Dr Farshid Rahimi Bashar

##### **Street address**

BESAT Hospital, General ICU, Motahhari

Avenue\_Resalat square

**City**

Hamedan

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences-vice  
chancellor for research

**Full name of responsible person**

Dr.Heidar Tavilani

**Street address**

Mahdiye Street, Hamedan University Of Medical  
Sciences

**City**

Hamedan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Hamedan University of Medical Sciences-vice chancellor  
for research

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Farshid Rahimi Bashar

**Position**

Assistant Professor/Intensive care fellowship

**Other areas of specialty/work**

**Street address**

Mahdiye Street, Hamedan University Of Medical  
Sciences

**City**

Hamedan

**Postal code**

**Phone**

+98 81 1821 4230

**Fax**

**Email**

fr\_rahimibashar@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Farshid Rahimi Bashar

**Position**

Assistant Professor/Intensive care fellowship

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*